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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

NEUER ET AL.

APPLICATION NO: 09/738,212

FILED: DECEMBER 15, 2000

FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617

Examiner: A. Berman

Assistant Commissioner for Patents
Washington, D.C. 20231

REPLY BRIEF

Sir:

This is response to the Examiner's Answer, dated January 15, 2003.

Regarding the groupings of the claims, since claim 33 was separately grouped by Appellants and separately argued (Brief at pages 2 and 4), it is deemed that this claim does not stand or fall with the others.

With regard to the obviousness rejection, it is reemphasized that the composition of the US'396 reference is physically different from that presently claimed. The Examiner states in the Answer that because the invention is drawn to a product, a future intended use cannot provide patentability. This misses the point of Appellants' argument, which is not that the claimed composition is unobvious based on its intended use when compared to a similar prior art composition. Claim 21 is directed to a hard gelatin capsule. In contrast, US '396 discloses a composition for intravenous administration, which is not a hard gelatin capsule. There is thus a clear physical difference between the subject matter claimed and the prior art. Appellants' argument is that it would not have been obvious to modify the US'396 formulation by encapsulation in a hard gelatin capsule. The point of the intended use argument is that a skilled person would only have encapsulated the prior art composition in a hard gel capsule if he thought that the intravenous formulation would be suitable for oral administration.

However, US '396 specifically sets out to provide a formulation adapted for intravenous administration, which is both a) clearly distinguished by the reference itself from the oral formulations discussed as prior art therein, and b) is suggested to be advantageous when compared thereto. To show how the prior art teaches away from the present invention, it is noted that US '396 goes on to discuss how cyclosporin formulations adapted for oral use are not suitable for intravenous administration (see column 1, lines 31 to 57). A person of ordinary skill would clearly understand that the converse was also true, namely that formulations for intravenous administration would not be suitable for oral use. In other words, the teaching of US'396 is that there is a dichotomy between formulations for oral and intravenous administration. The notable absence of any mention of oral use for the primary formulations of US '396 immediately suggests that such formulations would not be suitable for oral administration, because otherwise there would be no need to administer them intravenously. If it were obvious that a composition were able to achieve the same effects by oral administration as by intravenous administration, a skilled person would naturally select the oral route because of the convenience of administration.

Thus, the explicit selection of the intravenous route in the prior art document would suggest to a skilled person the exclusion of all other routes not mentioned. Because he would not expect that such formulations would be suitable for oral use, he would not formulate them into a hard gelatin capsule. The mere fact that other cyclosporin formulations, comprising different excipients, can be administered in hard gelatin capsules cannot overcome the above argument. The question is whether it would have been obvious to formulate the particular combination of excipients specified in the claim in a hard gelatin capsule comprising cyclosporin. As discussed above, in view of US '396 a skilled person would not expect such a combination to be suitable.

Respectfully submitted,

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Encl: Reply Brief in triplicate

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